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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,442	01/24/2001	Chun-Ying Huang	U 012951-1	2379

7590

01/18/2005

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EXAMINER

HARTLEY, MICHAEL G

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 01/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/768,442	Applicant(s) HUANG ET AL.	
	Examiner Michael G. Hartley	Art Unit 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 November 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 9 and 11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Response to Amendment***

The amendment filed 11/24/2004 has been entered. Claim 10 has been canceled.

Consequently, claims 9 and 11 are pending and have been examined herein.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9 and 11 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Lentz (US 6,231,536), for the reasons set forth in the office action mailed 5/24/2004.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amato (US 5,629,327) and Masiero (reference) and Patierno (US 5,696,092), for the reasons set forth in the office action mailed 11/21/2002.

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***Response to Arguments***

Any previous rejections not reiterated herein have been withdrawn.

Applicant's arguments filed 11/24/2004 have been fully considered but they are not persuasive.

Applicant asserts that the tumor therapeutic effects in example 4 of '536 occurred because of the ultrapheresis and should not be attributed to the administration of thalidomide.

This mere allegation is not supported. Clearly, the method of treating primary liver cancer (hepatocellular cancer) in example 4 shows administration of a composition "consisting essentially of" thalidomide, which "revealed further reduction in the tumors in the lung and liver" and therefore clearly does provide a therapeutic effect.

Applicant further asserts that the '536 method using ultrapheresis and is not a single administration.

This is not found persuasive because the claims do not exclude additional treatments as the claim is "A method for treating hepatocellular carcinoma comprising..." Also, the use of "consisting essentially of" does not limit administration to a single administration, but only possibly exclude other active cancer compositions being combined with thalidomide. It is noted that ultrapheresis is a method in which no composition is administered. In the methods of example 4 of '536, the pharmaceutical composition "consisted essentially of" thalidomide, as thalidomide is the only composition that is stated as being administered in example 4.

Applicant asserts that the '327 (citation 4) does not disclose that thalidomide can be used to treat cancer.

This is not found persuasive because the '327 patent specifically recites "It is yet another object of the present invention to provide treatment for solid tumors" in column 5, lines 23-24. This is clearly a method of treating cancer. Thus, the '327 discloses a generally method of treating cancers that are associated with angiogenesis by administration of thalidomide.

Applicant asserts that citations 4 through 6 in the 103 rejection provide no motivation or reasonable expectation of success in using thalidomide for hepatocellular cancer.

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This is not found persuasive because, as stated, citation 4 generally discloses treating solid tumors (cancer) that are associated with angiogenesis using thalidomide. Citation 4 provides a disclosure that thalidomide can be used to treat various cancers that have angiogenic behavior (e.g., that thalidomide is an anti-angiogenesis agent), while Masiero (citation 5) specifically teaches that thalidomide is used to treat prostate and breast cancer. Patierno (citation 6) teaches that liver cancers are specifically treatable with anti-angiogenesis agents and that such cancers respond in a similar fashion to such agents as compared to prostate cancer, etc, see columns 8-9. Thus, one of ordinary skill in the art would be motivated to employ the thalidomide disclosed as an anti-angiogenesis agent by citation 4 and as an anticancer agent by Masiero in various related cancers because it is known in the art that liver cancers (e.g., hepatocellular carcinoma) respond well to such anti-angiogenesis agents, thereby providing a useful treatment for such cancers with a reasonable expectation of success. Obviousness does not require absolute predictability. One of ordinary skill in the art of cancer treatment would have been motivated to use the anti-angiogenesis agent thalidomide as disclosed by citation 4 to its fullest potential to treat any cancers that respond to such agents.

### ***Conclusion***

No claims are allowed at this time.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

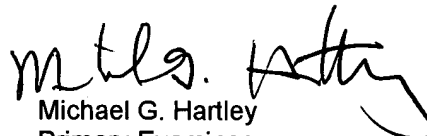
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

1/13/2005